Recommended Contents of a Sample eCTD Submission

Please follow the sample guidelines below so that we may provide you with a meaningful, comprehensive analysis of your submission and help to ensure you are able to submit according to specifications. *(Note: if you have already successfully submitted a sample eCTD, it is not necessary to submit a second sample.)* This validating phase does not involve any regulatory review of the content of the submission. It is intended only to resolve technical issues.

A single eCTD sample should include the following items and those items must comply with FDA and ICH specifications:

At a minimum Module 1 information should be included, but information in Modules 2-5 is recommended to be included	
Us-regional.xml according to **eCTD Backbone Files Specification for Module 1 DTD 3.3**	
Us-regional.xml and FDA form (e.g., 356h, 1571, or 3938) contain the same 6-digit application number, submission type, submission sub-type, and submission date. Submissions to NDA, BLA, ANDA and Commercial IND require an FDA fillable form.	
Submissions adhere to the **PDF Specifications –** pay close attention to:	
Bookmarks	
PDF document open properties	
Proper page rotation/page	
Display PDF file and folder	
Names	
Hypertext links adhere to the **eCTD Guidance**	
Study tagging files are used correctly	
Valid Values are used correctly for study components linked into study tagging files	
All submission documents adhere to **FDA** and **ICH** specifications	

Modules in the sample should contain the following:		
Module 1	Cover letter stating what type of sample you are submitting (eCTD, eCTD specific to study data validation, CDISC, Cross Application Linking)	
	The appropriate FDA form (e.g., 356h, 1571, or 3938)	
Module 2	Include at least one leaf	
Module 3	Include at least one leaf within the 3.2.p section with appropriate attributes applied	
Module 4	Include one study in section 4.2.3.1, 4.2.3.2, or 4.3.2.4. Refer to the **eCTD Backbone File Specification for Study Tagging Files**, the **Valid Values.xml**, and the **Specifications for eCTD Validation Criteria** listed in the eCTD Data Standards. Include the following data leafs:	
	data definition leaf (define.xml file)	
	a study report leaf	
	a dataset leaf (.xpt file)	
	To check non-standardized study information, submit at least one leaf to 4.2.1, 4.2.2, 4.2.3.3, 4.2.3.5, 4.2.3.6, or 4.2.3.7. Refer to the **eCTD Backbone File Specification for Study Tagging Files** and the **Valid Values.xml** listed in the eCTD Data Standards	
Module 5	Include one study in section 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, or 5.3.5.2. Refer to the **eCTD Backbone File Specification for Study Tagging Files**, the **Valid Values.xml**, and the **Specifications for eCTD Validation Criteria** listed in the eCTD Data Standards. Include the following data leafs:	
	at least one data definition leaf (define.xml file)	
	a study report leaf	
	at least one dataset leaf (.xpt file)	

	Include at least one annotated case report form (blank case report form). FDA does not use 5.3.7. Instead CRFs should be linked into the appropriate study tagging file. Refer to the **eCTD Backbone File Specification for Study Tagging Files** and the **Valid Values.xml** listed in the eCTD Data Standards	
	To check non-standardized study information, submit at least one leaf to 5.3.1.3, 5.3.1.4, 5.3.2, 5.3.3.5, 5.3.5.3, 5.3.5.4, or 5.3.6. Refer to the **eCTD Backbone File Specification for Study Tagging Files** and the **Valid Values.xml** listed in the eCTD Data Standards	

Cross Application Linking:

Cross application linking may be used for submissions where the same information needs to be submitted to multiple applications. It's possible to cross-link to different application type for example IND, NDA, BLA, ANDA or DMF.

The sample should contain two eCTD applications using two different sample application numbers. Refer to the eCTD sample submission recommendations for more specific content recommendation for each Module 1-5.	
One eCTD Application	
At a minimum Module 1 information should be included and the files which will be referenced, but information in Modules 2-5 is recommended to be included	
A second eCTD application	
At a minimum Module 1 information should be included and the files which reference the first eCTD application, but information in Modules 2-5 is recommended to be included	
Cross application leaf should have a clear leaf title for example <title> Container Closure - Cross Reference from Application A</title>	
M1 cross reference example xlink:href="../../applicationAtypexxxxxx/seq/folder/doc.pdf"	

Note: If we are unable to evaluate your sample, load it onto our server, perform eCTD validation, or cannot view the sample, you will be contacted and asked to resubmit according to specifications.

Submitting a successful sample will help ensure successful submissions in the future.

If you have questions about eCTD format, please contact the electronic submissions staff at esub-Testing@fda.hhs.gov

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